



EPW

THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of: **Stamm et al**

Application No. **10/665,517**

Filed: **September 22, 2003**

For: **Fenofibrate Compositions Having High Bioavailability**

Attorney Docket No: 107664.115US12

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Pursuant to 37 C.F.R. §§ 1.56, 1.97 and 1.98, Applicants bring to the attention of the Examiner the documents listed on the attached PTO-1449 Form.

Applicants also bring to the Examiner's attention the following litigations which involve one or more patents (e.g., one or more of US Patent Nos. 6,074,670, 6,277,405, 6,589,552, 6,652,881) to which the present application claims priority and/or is related:

1. *Abbott Laboratories et al v. Impax Laboratories*,
Delaware Court, Docket No. 1:04cv48.
2. *Abbott Laboratories et al v. Teva Pharmaceuticals*,
Delaware Court, Docket No. 1:04cv47.
3. *Abbott Laboratories et al v. Impax Laboratories*,
Delaware Court, Docket No. 1:03cv890.
4. *Abbott Laboratories v. Teva Pharmaceuticals*,
Delaware Court, Docket No. 1:03cv847.
5. *Abbott Laboratories v. Ranbaxy Pharmaceutic et al*,
New Jersey Court, Docket No. 3:03cv4067.
6. *Abbott Laboratories et al v. Ranbaxy Pharmaceutic et al*,
New Jersey Court, Docket No. 2:03cv2170.
7. *Abbott Laboratories et al v. Impax Laboratories*,
Delaware Court, Docket No. 1:03cv288.

8. *Abbott Laboratories et al, v. Par Pharmaceutical,*
New Jersey Court, Docket No. 2:03cv809.
9. *Abbott Laboratories et al v. Impax Laboratories,*
Delaware Court, Docket No. 1:03cv120.
10. *Abbott Laboratories et al v. Teva Pharmaceuticals,*
Delaware Court, Docket No. 1:02cv1512.
11. *Reliant Pharmaceuticals Inc. v. Abbott Laboratories, Inc. et al*
Delaware Court, Civil Action No. 04-350.

The submission of this Information Disclosure Statement does not represent that a search has been made and does not constitute an admission that the listed documents and/or litigations are material to patentability or that the listed documents are prior art.

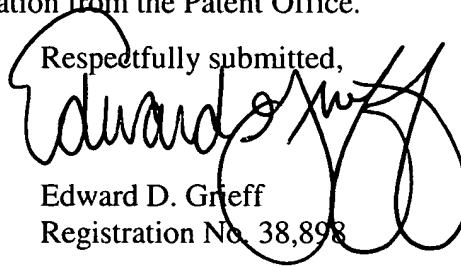
Since this application was filed after June 30, 2003, Applicants are not providing a copy of the cited US patent or US publications. A copy of the other cited documents listed on the PTO-1449 Form is submitted herewith.

With respect to the references cited in the PTO-1449 Form, Applicants note that EP 256 933 is equivalent to US Patent No. 4,800,079 (which is of record in the pending application); EP 330 532 is equivalent to US Patent No. 4,895,726 (which is of record in the pending application); and EP 761 208 is equivalent to US Patent No. 5,776,495 (which is of record in the pending application). WO 96/01621 is cited and discussed in the specification at page 4, lines 15-32. WO 98/31361 and EP 0 952 829 B1 are the PCT application and European patent, respectively, the specifications of which correspond to the present application and/or one or more patents and/or applications to which the present application claims priority and/or is related.

This Information Disclosure Statement is being filed before the mailing date of a first office action on the merits and before a notice of allowance. Accordingly, no fee is due. The Commissioner is authorized to charge any necessary fees or credit any overpayments to Deposit Account No. 08-0219.

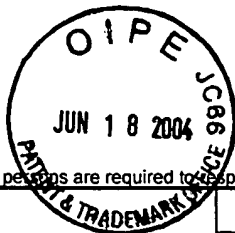
Applicants respectfully request that the Examiner initial and return a copy of the enclosed PTO-1449 Form with the next communication from the Patent Office.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Edward D. Grieff', written over the typed name and registration number.

Edward D. Grieff
Registration No. 38,898

Date: June 18, 2004
WILMER CUTLER PICKERING
HALE AND DORR LLP
1455 Pennsylvania Avenue, NW
Washington, DC 20004
Phone: (202) 942-8400



Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet

1

of

2

Complete if Known

| | |
|------------------------|--------------------|
| Application Number | 10/665,517 |
| Filing Date | September 22, 2003 |
| First Named Inventor | Stamm |
| Art Unit | |
| Examiner Name | |
| Attorney Docket Number | 107664.115 US12 |

U. S. PATENT DOCUMENTS

| Examiner Initials* | Cite No. ¹ | Document Number | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
|-----------------------|--------------------------|--|-----------------------------------|--|---|
| | | Number-Kind Code ² (if known) | | | |
| | | US- 2004/0092597 | 05-13-2004 | Stamm et al | |
| | | US- 2004/0058005 | 03-25-2004 | Stamm et al | |
| | | US- 2004/0058004 | 03-25-2004 | Stamm et al | |
| | | US- 2004/0057999 | 03-25-2004 | Stamm et al | |
| | | US- 2004/0057998 | 03-25-2004 | Stamm et al | |
| | | US- 2004/0057997 | 03-25-2004 | Stamm et al | |
| | | US- 2003/0104060 | 06-05-2003 | Stamm et al | |
| | | US- 2003/0104051 | 06-05-2003 | Stamm et al | |
| | | US- 2002/0168413 | 11-14-2002 | Stamm et al | |
| | | US- 2002/0114839 | 08-22-2002 | Stamm et al | |
| | | US- 2002/0009496 | 01-24-2002 | Stamm et al | |
| | | US- 5,073,379 | 12-17-1991 | Klimesch et al | |
| | | US- | | | |
| | | US- | | | |
| | | US- | | | |
| | | US- | | | |
| | | US- | | | |
| | | US- | | | |
| | | US- | | | |

FOREIGN PATENT DOCUMENTS

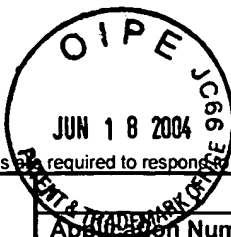
| Examiner Initials* | Cite No. ¹ | Foreign Patent Document | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear | T ⁶ |
|-----------------------|--------------------------|---|-----------------------------------|--|---|----------------|
| | | Country Code ³ -Number ⁴ -Kind Code ⁵ (if known) | | | | |
| | | EP 0 952 829 B1 | 03-05-2003 | Stamm et al | | |
| | | EP 0 761 208 A1 | 03-12-1997 | Duclos et al | | |
| | | WO 98/31361 | 07-23-1998 | Stamm et al | | |
| | | WO 96/01621 | 01-25-1996 | Stubberud et al | | |
| | | WO 82/01649 | 05-27-1982 | Laruelle | | |
| | | | | | | |

Examiner
SignatureDate
Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.



PTO/SB/08B (08-03)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Complete if Known

| | |
|------------------------|--------------------|
| Apparatus Number | 10/665,517 |
| Filing Date | September 22, 2003 |
| First Named Inventor | Stamm |
| Art Unit | |
| Examiner Name | |
| Attorney Docket Number | 107664.115 US12 |

Sheet

2

of

2

NON PATENT LITERATURE DOCUMENTS

| Examiner Initials* | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T ² |
|--------------------|-----------------------|---|----------------|
| | | Complaint, US District Court for the District of Delaware, Civil Action No. 04-350, Reliant Pharmaceuticals v. Abbott Laboratories et al (1 June 2004). | |
| | | Opposition to EP 0 952 829 (December 11, 2003) (English language translation). | ✓ |
| | | Opposition to EP 0 952 829 (December 11, 2003) (original French language document). | |
| | | Handbook of Pharmaceutical Excipients, Second Edition, pages 392-399 (1994). | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |

Examiner
Signature

Date

Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.